

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

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This Document Relates to:  
All Cases

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) MDL No. 1:13-md-2419-RWZ  
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**NECC’S CHAPTER 11 TRUSTEE’S OBJECTIONS  
TO THE TENNESSEE CLINIC DEFENDANTS’ SUBPOENA *DUCES TECUM***

Pursuant to Rule 45 of the Federal Rules of Civil Procedure, Frederick H. Fern of Harris Beach PLLC, Specially Retained Counsel for Paul D. Moore, the Chapter 11 Trustee for the bankruptcy Estate of New England Compounding Pharmacy, Inc. (“NECC”), submits these Responses and Objections to Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively “Tennessee Clinic Defendants”) Subpoena *Duces Tecum* dated April 17, 2015, and further responds as follows:

**PRELIMINARY STATEMENT**

NECC has produced over 32,000 pages of documents in this litigation that are easily accessible by the Tennessee Clinic Defendants via the US Legal Repository. Rather than review those documents already produced and available to determine which they deem relevant, the Tennessee Clinic Defendants are attempting to shift their burden to NECC to identify documents for the Tennessee Clinic Defendants to be used in this litigation. NECC has no obligation to perform such an overwhelming task on behalf of the Tennessee Clinic Defendants, and any such request is overly broad, unduly burdensome, and beyond the scope of discovery permitted by the

Court's October 9, 2014 Order (MDL Doc. No. 1482).

Further, the Tennessee Clinic Defendants' Requests are unreasonably duplicative in clear violation of Rule 26 of the Federal Rules of Civil Procedure prohibiting duplicative discovery. *See* Fed. R. Civ. P. 26(b)(2)(C)(i). Responses and answers to the same can be obtained from other sources that are more convenient, less burdensome, and less expensive than from NECC. Specifically, documents responsive to the Tennessee Clinic Defendants' Requests can be located in the US Legal Repository among the 32,000+ pages of documents NECC has already produced.

Notwithstanding these objections, NECC will produce documents responsive to these Requests under separate cover via a password-secured FTP site.

### **GENERAL OBJECTIONS**

The following General Objections are set forth below in lieu of restating each general objection in response to each Request posited by the Tennessee Clinic Defendants. Each objection is therefore incorporated by reference into each individual Response herein. Failure to assert any specific objection in response to these Requests does not waive any objection, and NECC reserves the right to later assert any objection to any Request. Asserting a specific objection in response to any of these Requests does not waive NECC's rights to assert any appropriate general objection thereto. NECC further expressly reserves the right to object to the use of these Responses as evidence for any purpose including, but not limited to, the use of these Responses in any subsequent proceeding or in the trial of this or any other action. The objections herein are set forth without prejudice to NECC's right to supplement or amend any responses at any time prior to trial.

1. NECC objects to each Request to the extent it is beyond the scope of discovery permitted by the Court's October 9, 2014 Order regarding limitations on discovery obligations. *See* MDL Doc. No. 1482, at ¶ 6 (permitting discovery "only to the extent the discovery is relevant to the prosecution, or defense, of claims against defendants other than the Estate Parties or the Insider Settling Parties").

2. NECC objects to each Request to the extent it seeks discovery from NECC in violation of the automatic bankruptcy stay. *See In re Alem*, No. 13-00119, 2013 WL 4840486, at \*2 (Bankr. D.D.C. Sept. 10, 2013).

3. NECC objects to any terms or instructions which would broaden the obligation imposed on it by the Federal Rules of Civil Procedure in responding to demands for documents.

4. NECC objects to each Request to the extent it seeks documents previously produced in this litigation in violation of Rule 26 of the Federal Rules of Civil Procedure prohibiting duplicative discovery.

5. NECC objects to each Request to the extent it seeks information that is not relevant to the prosecution or defense of claims asserted by the Tennessee Clinic Defendants, specifically relating to comparative fault claims.

6. NECC objects to each Request to the extent it does not allow sufficient time to comply.

7. NECC objects to each Request to the extent it seeks information irrelevant to this litigation and to the extent such requests are not reasonably calculated to lead to the discovery of admissible evidence. *United States v. Justice*, 14 F. App'x 426, 433 (6th Cir. 2001) ("A subpoena *duces tecum* must be reasonable, specific, and the documents requested must be relevant.")

8. NECC objects to each Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit.

9. NECC objects to each Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation.

10. NECC objects to each Request to the extent it requires disclosure of items protected by the attorney-client privilege, the work product privilege, and/or any other privilege, protection, or immunity.

11. NECC objects to each Request to the extent it seeks items prepared in anticipation of litigation or in the course of trial preparation.

12. NECC objects to each Request to the extent it subjects NECC to undue burden or expense.

13. NECC objects to each Request to the extent it contains requests that are so vague and ambiguous that it is unreasonable or even impossible for NECC to comply.

14. NECC objects to each Request to the extent it is so overly broad and burdensome as to render it impossible to respond in any reasonable manner or amount of time.

15. NECC objects to each Request to the extent it seeks items regarding present or former employees, shareholders, vendors, or other business associates (collectively, “Business Associates”) of NECC not parties to this lawsuit. Requests for such information impose an unreasonable burden upon NECC as they would require it to conduct a search of unreasonable scope. Moreover, such information is confidential and may include proprietary information about Business Associates and, as such, Business Associates might have a right, under applicable federal and/or state law, to have notice of the Requests and an opportunity to object to the Requests before any item could be revealed.

16. NECC objects to each Request to the extent it requires disclosure of a trade secret or other confidential and/or proprietary business information of NECC or NECC's Business Associates, and/or other items of such character.

17. NECC objects to each Request to the extent it seeks disclosure of information protected under the Health Insurance Portability and Accountability Act ("HIPAA") and its related regulations.

18. NECC objects to each Request to the extent it seeks any information already in the possession of Tennessee Clinic Defendants or their counsel, which already has been provided to Tennessee Clinic Defendants or their counsel by others, or which is obtainable from the public record in a manner that makes the process of retrieving such information equally available to Tennessee Clinic Defendants.

19. NECC objects to each Request to the extent it seeks information that is not in the possession, custody, or control of NECC.

20. By responding to any of the Requests, NECC does not thereby incorporate Tennessee Clinic Defendants' Instructions, or Tennessee Clinic Defendants' actual or apparent understanding of any word or term.

21. NECC objects to the use of the words "any" and/or "all" in each Request to the extent it imposes or can be construed to impose a burden upon NECC great than that imposed by applicable statutes, court rules, and/or decisional law.

**RESPONSES AND SPECIFIC OBJECTIONS TO DOCUMENT REQUESTS**

1. The personnel files for:
  - a. Barry Cadden
  - b. Glenn Chin
  - c. Gene Svirskiy
  - d. Christopher Leary
  - e. Joseph Evanosky
  - f. Scott Connolly
  - g. Joseph Connolly
  - h. Sharon Carter
  - i. Alla Stepanets
  - j. Greg Conigliaro
  - k. Robert Ronzio
  - l. Kathy Chin
  - m. Michelle Thomas
  - n. Carla Conigliaro
  - o. Doug Conigliaro
  - p. Any other person involved in the manufacture or compounding of batches 05212014@68; 06292012@26; 08102012@51.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request as personnel files are confidential and the Tennessee Clinic Defendants have not demonstrated that the potential relevancy of the files outweigh the privacy interests of the individuals. *Whittingham v. Amherst Coll.*, 164 F.R.D. 124, 128 (D. Mass. 1995) (citing *Miles v. Boeing, Co.*, 154 F.R.D. 112, 115 (E.D. Pa. 1994) (personnel files are confidential and discovery of them should be limited), and *Gehring v. Case Corp.*, 43 F.3d 340, 342 (7th Cir. 1994) (affirming lower court decision that releasing personnel files of others would violate privacy interests)). NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

2. Documents related to internal or external sterility testing of batches 05212012@68; 06292012@26; 08102012@51.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. NECC objects to this Request to the extent it seeks disclosure of documents or information pertaining to NECC’s Business Associates. Notwithstanding these objections, NECC responds that it has produced the Logged Formula Worksheets (“LFW”) and ARL testing results for all three lots and a responsive e-mail as set forth below:

<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
05212012@68 LFW and ARL results	NECC_MDL000005160-5166	8/23/13
06292012@26 LFW and ARL results	NECC_MDL000005167-5172	8/23/13
08102012@51 LFW and ARL results	NECC_MDL000013368-13372	9/11/13
9/21/12 email chain between Sharon Carter and Mario Giamei	NECC_MDL000024698-24700	9/24/13

NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

3. Any corporate minutes, memoranda, or meeting summaries from corporate meetings from 2006 through the outbreak related to:
- Problems with NECC’s sterility processes
  - The use of patient-specific prescriptions or patient name lists in the ordering process
  - The Tennessee Clinic Defendants.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or

transactions beyond the scope of this litigation. Notwithstanding these objections, NECC responds that after a diligent search, no documents responsive to this Request were identified. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

4. Any customer file maintained for any of the Tennessee Clinic Defendants.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. Notwithstanding these objections, NECC responds that because this Request is too broad to conduct a reasonable search for responsive documents, NECC is willing to meet and confer with the Tennessee Clinic Defendants to narrow this Request in order to identify potentially responsive documents. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

5. Any internal communications or memoranda mentioning the Tennessee Clinic Defendants from prior to September 20, 2012.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. Notwithstanding these objections, NECC responds that because this Request is too broad to conduct a reasonable search for responsive documents, NECC is willing to meet and confer with the Tennessee Clinic Defendants to narrow this Request in order to identify potentially responsive documents. Further, NECC responds that it has produced communications with the Tennessee Clinic Defendants as set forth below:



<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
8/31/12 MPA invoice to STOPNC with prescription order form signed by John Culclasure	NECC_MDL000013147-13150	9/11/13
7/10/12 email chain between Mario Giamei and Jean Atkinson	NECC_MDL000027224-27229; NECC_MDL000027235-27245	11/1/13

**NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.**

6. Any letters, emails, faxes, or documentation of phone conversations with the Tennessee Clinic Defendants.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. Notwithstanding these objections, NECC responds that because this Request is too broad to conduct a reasonable search for responsive documents, NECC is willing to meet and confer with the Tennessee Clinic Defendants to narrow this Request in order to identify potentially responsive documents. Further, NECC responds that it has produced a customer complaint record pertaining to the Tennessee Clinic Defendants as set forth below:

<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
9/20/12 Customer Complaint Record from Cindy McClendon of STOPNC	NECC_MDL000013165-13168	9/11/13

**NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.**

7. Any documents related to site visits or inspections conducted by customers of NECC from 2006 to the time of the outbreak.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. NECC objects to this Request to the extent it seeks disclosure of documents or information pertaining to NECC’s Business Associates. Notwithstanding these objections, NECC responds that because this Request is too broad to conduct a reasonable search for responsive documents, NECC is willing to meet and confer with the Tennessee Clinic Defendants to narrow this Request in order to identify potentially responsive documents relating to the Tennessee Clinic Defendants. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

8. Any internal documents reflecting NECC’s failure to comply with USP 797 in the compounding of sterile medications prior to September 18, 2012.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

9. Any internal documents, memoranda, or emails reflecting training or instruction to NECC sales people or discussions among NECC employees related to whether a customer was required to send a patient-specific prescription or a list of patient names.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. Notwithstanding these objections, NECC responds that because this Request is too broad to conduct a reasonable search for responsive documents, NECC is willing to meet and confer with the Tennessee Clinic Defendants to narrow this Request in order to identify potentially responsive documents relating to the Tennessee Clinic Defendants. Further, NECC responds that it has produced emails responsive to this request as set forth below:

<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
7/10/12 email chain between Mario Giamei and Jean Atkinson	NECC_MDL000027224-27229; NECC_MDL000027235-27245	11/1/13
8/9/11 email chain between Cadden and Zachary Pratico	NECC_MDL000011001	9/11/13

NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

10. Copies of the emails referenced in Paragraphs 92-101 of the NECC Criminal Complaint.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. Notwithstanding these objections, NECC will produce the emails referenced in Paragraphs 92-101 of the NECC Criminal Complaint via the FTP site. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

11. Copies of the emails and external communication referenced in Paragraphs 104-08 of the NECC Criminal Complaint.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. Notwithstanding these objections, NECC will produce documents referenced in Paragraphs 104-08 of the NECC Criminal Complaint via the FTP site. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

12. Any communications from customers or potential customers of NECC from 2006 to the time of the outbreak inquiring as to:
  - a. Whether it made and sold its medications in compliance with all applicable pharmaceutical laws
  - b. Its regulator history, including recalls, licensure actions, and investigations
  - c. Its history of product liability suits
  - d. Its ordering process (specifically whether it required patient-specific prescriptions when filling orders for medications and whether this was necessary to comply with state or federal law)
  - e. Beyond-use dates and recommended storage of MPA
  - f. Whether NECC, prior to September 2011, was a reputable supplier of medications.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. NECC objects to this Request to the extent it seeks disclosure of documents or information pertaining to NECC’s Business Associates.

Notwithstanding these objections, NECC responds that because this Request is too broad to conduct a reasonable search for responsive documents, NECC is willing to meet and confer with the Tennessee Clinic Defendants to narrow this Request in order to identify potentially responsive documents relating to the Tennessee Clinic Defendants. Further, NECC responds that it has produced emails responsive to this request as set forth below:

<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
7/10/12 email chain between Mario Giamei and Jean Atkinson	NECC_MDL000027224-27229; NECC_MDL000027235-27245	11/1/13
8/9/11 email chain between Cadden and Zachary Pratico	NECC_MDL000011001	9/11/13
7/12/12 email from Steven Howell to NECC	NECC_MDL000024153-24156	9/17/13

NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

13. Documents in NECC's possession reflecting the due diligence conducted by the following health care institutions before purchasing from NECC:
  - a. University of Pittsburgh Medical Center - Pittsburgh, PA
  - b. New York Presbyterian — Weill Cornell - New York, NY
  - c. Mayo Clinic Health System in Fairmont - Fairmont, MN
  - d. Massachusetts General Hospital - Boston, MA
  - e. Brigham and Women's Hospital - Boston, MA
  - f. Northwestern Memorial Hospital - Chicago, IL
  - g. University of California, San Francisco Medical Center - San Francisco, CA
  - h. Vanderbilt Medical Group Clinic Pharmacy - Nashville, TN
  - i. Erlanger Health System - Chattanooga, TN
  - j. Centennial Medical Center - Nashville, TN
  - k. Gateway Medical Center - Clarksville, TN
  - l. Summit Surgery Center - Hermitage, TN

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled "General Objections." NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court's October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent

it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. NECC objects to this Request to the extent it seeks disclosure of documents or information pertaining to NECC's Business Associates. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

14. Order forms for orders of MPA in 2011-12 by the following NECC customers:

- a. University of Pittsburgh Medical Center - Pittsburgh, PA
- b. New York Presbyterian — Weill Cornell - New York, NY
- c. Mayo Clinic Health System in Fairmont - Fairmont, MN
- d. Massachusetts General Hospital - Boston, MA
- e. Brigham and Women's Hospital - Boston, MA
- f. Northwestern Memorial Hospital - Chicago, IL
- g. University of California, San Francisco Medical Center - San Francisco, CA
- h. Vanderbilt Medical Group Clinic Pharmacy - Nashville, TN
- i. Erlanger Health System - Chattanooga, TN
- j. Centennial Medical Center - Nashville, TN
- k. Gateway Medical Center - Clarksville, TN
- l. Summit Surgery Center - Hermitage, TN

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled "General Objections." NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court's October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information or documents concerning events, individuals, and/or transactions beyond the scope of this litigation. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. NECC objects to this Request to the extent it seeks disclosure of information protected under HIPAA and its related regulations. NECC objects to this Request to the extent it seeks disclosure of documents or information pertaining to NECC's Business Associates. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.



15. Copies of the Quarterly Assurance Report Cards for all quarters in 2009-12.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. Notwithstanding these objections, NECC will produce the Quality Assurance Report Cards for 2011 and 2012 via the FTP site. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

16. The cleaning logs for Cleanroom 1 from 2010-12.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks disclosure of documents or information pertaining to NECC’s Business Associates. Notwithstanding these objections, NECC will produce the UniClean cleaning logs for Cleanroom 1 for 2012 via the FTP site. NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

17. Surface and air testing or sampling results (including gloved fingertip sampling results) from 2010-12.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. Notwithstanding these objections, NECC responds that it has produced surface and air testing results for 2012 as set forth below:

<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
6/22/12 Scientific Air Analysis testing results	NECC_MDL000000348-353	7/16/13
9/26/12 air sample results	NECC_MDL000032785-32791	3/9/15
2012 surface and air testing for Cleanroom 1	NECC_MDL000032701-32768	10/1/14

NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

18. Autoclaving records for batches 05212012@68; 06292012@26; 08102012@51.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. Notwithstanding these objections, NECC responds that it has produced LFWs with autoclave results for all three lots as set forth below:

<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
05212012@68 LFW and ARL results	NECC_MDL000005160-5166	8/23/13
06292012@26 LFW and ARL results	NECC_MDL000005167-5172	8/23/13
08102012@51 LFW and ARL results	NECC_MDL000013368-13372	9/11/13

NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

19. A copy of NECC’s standard operating procedures or other internal policies or procedures related to the following:

- a. The ordering process
- b. Marketing of its medications to health care provider customers
- c. Production of sterile medications
- d. Maintaining the sterility of the NECC environment.

**Response:** NECC objects to this Request on each of the grounds set forth in the above section entitled “General Objections.” NECC further objects to this Request to the extent it is beyond the scope of discovery permitted by the Court’s October 9, 2014 Order. NECC



objects to this Request to the extent it seeks disclosure of documents not relevant to the comparative fault claims alleged by the Tennessee Clinic Defendants. NECC also objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous, unreasonable, evidentiary in nature, and/or beyond the scope of a subpoena *duces tecum*. NECC objects to this Request to the extent it seeks items pertaining to a period of time beyond the scope of the time period relevant to this lawsuit. NECC objects to this Request to the extent it seeks information within the possession, custody, and/or control of another party, and/or has previously been produced in this litigation. Notwithstanding these objections, NECC responds that it has produced a complete set of NECC's SOPs and additional procedures as set forth below:

<u>Document</u>	<u>Bates Range</u>	<u>Production Date</u>
Complete SOP set	NECC_MDL000027735-28016	11/1/13
General Overview of Policies & Procedures for Compounding Sterile Products	NECC_MDL000011219-11220	9/11/13

NECC reserves the right to amend and/or supplement this response as additional information becomes available up until and including the time of trial.

Dated: May 1, 2015

Respectfully submitted,

**HARRIS BEACH PLLC**

/s/ Frederick H. Fern

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Pharmacy, Inc. d/b/a New England  
Compounding Center*

**Certificate of Service**

I, Frederick H. Fern, hereby certify that on this day, May 1, 2015, I caused a copy of the foregoing document, which was filed using this Court's ECF system, to be served electronically upon those parties registered to receive ECF service.

/s/ Frederick H. Fern  
Frederick H. Fern